

<u>IN THE UNITED STATES PATENT AND TRADEMARK OFFICE</u>

In re United States Patent Application of:

Application No.:

10/732,783

Hone, et al.

Date Filed:

Applicant:

December 10, 2003

Title:

TREATMENT AND PREVENTION OF **IMMUNODEFICIENCY** VIRUS INFECTION BY **ADMINISTRATION OF NON-**PYROGENIC DERIVATIVES

OF LIPID A

Docket No.:

4115-122 DIV 2

Examiner:

Not Yet Assigned

Art Unit:

Not Yet Assigned

Conf. No.:

Not Yet Assigned

Customer No.:

23448

23448

FIRST CLASS MAIL CERTIFICATE

I hereby certify that I am mailing the attached documents to the Commissioner for Patents on the date specified, in an envelope addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, and First Class Mailed under the provisions of 37 CFR 1.8.

Candace White

March 16, 2004

Date of Mailing

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449.

Applicants submitted an Information Disclosure Statement on December 4, 1998 and a Supplemental Information Disclosure Statement on February 20, 2001 in the parent application U.S. Patent Application No. 08/938,106 filed on September 26, 1997, now U.S. Patent No. 6,368,604. Additionally, applicants submitted an Information Disclosure Statement on February 26, 2001 and a Supplemental Information Disclosure Statement on October 9, 2001 in the divisional patent application of the parent application, U.S. Patent Application No. 09/383,709 filed on August 26, 1999. Copies of all references recited on the enclosed PTO Form 1449 have been previously submitted to the United States Patent and Trademark Office. All references cited by the UPSTO previously are attached.

⊠ 1.		formation Disclosure Statement is being filed within three months of the U.S. filing date fore the mailing date of a first Office Action on the merits. No certification or fee is d.
<u> </u>	date A	formation Disclosure Statement is being filed more than three months after the U.S. filing ND after the mailing date of the first Office Action on the merits, but before the mailing a Final Rejection or Notice of Allowance.
	☐ a.	I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(1).
	□ b.	I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).
	_ c.	Attached is our check no in the amount of \$ in payment of the fee under 37 C.F.R. §1.17(p). Please credit or debit Deposit Account No as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
date and after the mailing date of a Final Rejection or Notice of Allowance, but be of the Issue Fee. Applicant(s) hereby petition(s) that the Information Disclosure considered. Attached is our check no in the amount of \$180.00 in payment of the under 37 C.F.R. §1.17(i)(1). Please credit or debit Deposit Account No		formation Disclosure Statement is being filed more than three months after the U.S. filing d after the mailing date of a Final Rejection or Notice of Allowance, but before payment Issue Fee. Applicant(s) hereby petition(s) that the Information Disclosure Statement be red. Attached is our check no in the amount of \$180.00 in payment of the petition ler 37 C.F.R. §1.17(i)(1). Please credit or debit Deposit Account No as needed to consideration of the disclosed information. Two duplicate copies of this paper are d.
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	□ b.	I hereby certify that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. §1.97(e)(2).

Respectfully submitted,

Marianne Fuierer

Reg. No. 39,983 Attorney for Applicants

INTELLECTUAL PROPERTY/ TECHNOLOGY LAW Telephone: (919) 419-9350 Fax: (919) 419-9354 Attorney Ref: 4115-122 DIV 2

PTO/SB/08A (01-04)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION
DISCLOSURE STATEMENT
BY APPLICANT

Sheet 1 of 5

persons are required to respond to a collection of information unless it contains a valid OMB control number.				
COMPLETE IF KNOWN				
Application Number	10/732,783			
Filing Date	December 10, 2003			
First Named Inventor	HONE, et al.			
Art Unit	Unassigned			
Examiner Name	Unassigned			
Attorney Docket Number	4115-122-DIV2			

		ENT DOCUMENTS	-			
Cite No.	Document Number	Publication Date MM-DD-YYYY	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		
AA	US-5,997,881		12-07-1999	Powell et al.		
AB	US-5,510,119		04-23-1996	Santus et al.	-	
AC	US-5,191,072		03-02-1993	Hasegawa et al		
AD	US-5,593,969		01-14-1997	Kamireddy et a	1.	
AE	US-5,597,573	<u> </u>	01-28-1997	Kamireddy et a	1.	
AF	US-5,158,939		10-27-1992	Takayama et al		
AG	US-5,189,674		02-23-1993			
-	FOREIGN I	PATENT DOCUME	NTS			
Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	661 15		lation NO ¹	
AH	WO 97/08955	03-13-1997				
AI	WO 91/16449	10-13-1991				
AJ	JP-A-63010728	01-18-1998				
AK	WO97/18837	05-29-1997				
AL	WO94/21292	09-29-1994				
AM	WO95/23156	08-31-1995				
AN	WO84/04526	11-22-1984				
	No. AA AB AC AD AE AF AG Cite No. AH AI AJ AK AL AM	No. Document Number AA US-5,997,881 AB US-5,510,119 AC US-5,191,072 AD US-5,593,969 AE US-5,597,573 AF US-5,158,939 AG US-5,189,674 FOREIGN F Cite No. Foreign Patent Document AH WO 97/08955 AI WO 91/16449 AJ JP-A-63010728 AK WO97/18837 AL WO94/21292 AM WO95/23156	No. Document Number AMM-DD-YYYY AA US-5,997,881 AB US-5,510,119 AC US-5,191,072 AD US-5,593,969 AE US-5,597,573 AF US-5,158,939 AG US-5,189,674 FOREIGN PATENT DOCUME Cite No. Foreign Patent Document Publication Date MM-DD-YYYY AH WO 97/08955 AI WO 91/16449 AJ JP-A-63010728 AK WO97/18837 AL WO94/21292 AM WO95/23156 Document Number MM-DD-YYYY DOCUME O3-13-1997 O3-13-1997 O5-29-1994 O5-29-1994 O8-31-1995	No. Document Number Tubilitation Date MM-DD-YYYY Issue Date MM-DD-YYYY AA US-5,997,881 12-07-1999 AB US-5,510,119 04-23-1996 AC US-5,191,072 03-02-1993 AD US-5,593,969 01-14-1997 AE US-5,597,573 01-28-1997 AF US-5,158,939 10-27-1992 AG US-5,189,674 02-23-1993 FOREIGN PATENT DOCUMENTS Cite No. Foreign Patent Document Publication Date MM-DD-YYYY Name of Pater of Cited AH WO 97/08955 03-13-1997 01-18-1998 AI WO 91/16449 10-13-1991 01-18-1998 AK WO97/18837 05-29-1997 09-29-1994 AL WO94/21292 09-29-1994 08-31-1995	No. Document Number AMM-DD-YYYY AM-DD-YYYY Cited D AA US-5,997,881 12-07-1999 Powell et al. AB US-5,510,119 04-23-1996 Santus et al. AC US-5,191,072 03-02-1993 Hasegawa et al. AD US-5,593,969 01-14-1997 Kamireddy et a. AE US-5,597,573 01-28-1997 Kamireddy et a. AF US-5,158,939 10-27-1992 Takayama et al. AG US-5,189,674 02-23-1993 FOREIGN PATENT DOCUMENTS Cite No. Foreign Patent Document Publication Date MM-DD-YYYY of Cited Document AH WO 97/08955 03-13-1997 AI WO 91/16449 10-13-1991 AJ JP-A-63010728 01-18-1998 AK WO97/18837 05-29-1997 AL WO94/21292 09-29-1994 AM WO95/23156 08-31-1995	No. Document Number

Examiner	Date	
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^{*}Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

¹ All the foreign patents and publications that are not written in English language are accompanied by their respective English abstracts, which constitute concise explanation of relevance of the non-English patents and publications that satisfy the requirements of 37 C.F.R. §1.98(a)(3)(i), according to MPEP 609 III A(3).



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Examiner Initials*	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Trans YES	Translation YES NO	
	AO	WO92/00101	01-09-1992				
	AP	WO92/06113	04-16-1992	V			
	AQ	0 668 289 A1	08-23-1995				
	AR	0 536 969 A2	04-14-1993				
	AS	0 437 016 A2	07-17-1991				
	AT	2 220 211 A	01-04-1990				
	AU	WO97/25061	07-17-1997				
	AV						
		NON-PATENT L	ITERATURE DOC	UMENTS			
Examiner Initials*	No.	number(s), publisher, city and/or country where published AW Bernstein, et al., 1991, J. Clinical invest. 88:540		oriate), title	e T ²		
3	AX	Begrasra, et al., 1992, Proc. Natl. A		W		┿	
	AY AZ	Bhat et al., Glyco Biology 2:535-539 (1992) Bunnell et al., Crit. Care Med. Suppl. 23:147 (1995)					
	BA	Bunnell et al., Crit. Care Med. Suppl. 23:147 (1995) Bunnell et al., Crit. Care Med. Suppl. 23:A151 (1995)					
	BB	Chemical Abstracts, Vol. 109, No. Derivatives as Analgesics"		, Abstract No. 163524, "Disac	charide		
	BC	Christ et al., J. Am. Chem. Soc. 116	5:3637 (1994)			╅	
BD Darveau et al., "Ability of Bacteria Associated With Chronic Inflammatory Disease to Stimula E-Selectin Expression and Promote Neutrophil Adhesion", Infect. And Immun. 63:1311-1317 (1995).							
	BE	Erwin and Munford, J. Biol. Chem. 256:16444 (1990)					
	BF	Fagan et al., J. Immunol. 153:5230 (1994)					
Examiner signature				Date Considered			

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	NON-PATENT LITERATURE DOCUMENTS				
Examiner Initials*	and the state of the walker (in oral 110B EE1 1ER5), title of the afficie (when appropriate), the		T ²		
	BG	Flexner, C. and C. Hendrix, 1997, "Pharmacology of antiretroviral agents," in AIDS: Biology, Diagnosis, Treatment and Prevention, fourth edition, DeVita, J., V., et al., eds., Lippincott-Raven Publishers, pp. 479-493			
	ВН	Friedman et al., "Immunodeficiency of Endotoxins and Nontoxic Derivatives for Normal and Leukemic Immunocytes" Advances in Exp. Med. and Biol., Vol. 256, (1990) pp. 525-535.			
	BI	Gait, M. and J. Karn, 1995, "Progress in anti-HIV structure-based drug design," TIBTECH 13(10):430-438			
		Golenback et al., J. Biol. Cehm. 266:19490 (1991)	-		
		International Search Report dated 17/03/99, for PCT/US98/20264, filed 28/09/98			
	BL	Johnson et al., "Characterization of a Nontoxic Monophosphoryl Lipid A," Review of Infectious Diseases, Vol. 9, No. S5 (1987) pp. S512-S516.			
	BM	Karow et al., J. Bacteriol., 173:741-750 (1991)			
	BN	Karow et al., "Isolation and Characterization of the <i>Escherischia coli</i> msbB Gene, a Multicopy Suppressor of Null Mutations in the High-Temperature Requirement Gene <i>htrB</i> ," J. Bacteriology, 174:702-710 (1992)			
	ВО	Karow et al., "The Lethal Phenotype Caused by Null Mutations in the <i>Escherichia coli htrB</i> Gene is Suppressed by Mutations in the accBC Operon, Encoding Two Subunits of Acetyl Coenzyme A Carbohydrate," J. Bacteriol. 174:7407 (1992).			
	BP Kornbluth et al., J. Exp. Medicine 169:1137 (1989).				
	BQ Kotani et al., Infect. Immun. 49:225 (1985)				
	BR Kovach et al., J. Exp. Med. 172:77-84 (1990).				
	BS	Munford and Hall, J. Biol. Chem. 264:15613 (1989).			

Examiner	Date	
signature	 Considered	

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	ВТ	Neter et al., J. Immunol. 76:377 (1956).	
	BU	Öberg, B. and L. Vrang, 1990, "Screening for new agents," Eur. J. Clin. Microbiol. Infect. Dis. 9(7):466-471	
_	BV	Perera et al., Infect. Immun. 61:2015 (1993).	
	BW	Qureshi et al., J. Biol. Chem. 263:5502 (1988)	
	BX	Qureshi et al., J. Biol. Chem. 266:6532 (1991).	
	BY	Raetz et al., J. Bacteriol. 175:5745-5753 (1993).	
	BZ	Rietschal et al., FASEB J. 8:217-225 (1994).	
	CA	Salimath et al., Eur. J. Biochem. 136:195 (1983)	
	CB	Sica et al., J. Exp. Med. 185:969 (1997).	
	CC	Ulmer et al., Infect Immun. 60(12):5145-5152 (1992).	
	CD	Wang et al., Infect. Immun. 59(12):4655-4664 (1991).	
	CE	Yarchoan, R. and S. Broder, 1992, "Correlations between the <i>in vitro</i> and <i>in vivo</i> activity of anti-HIV agents: implications for future drug development," J. Enzym, Inhib. 6:99-111.	
	CF	Cornelis, P. et al., 1992, "Stability, frequency, and multiplicity of transposon insertions in the pyoverdine region in the chromosomes of different fluorescent psuedomonads", J.Gen. Microbiol. 138:1337-1343	
	CG	Pries, A., et al., 1992, "Indentification of a lipoamide dehydrogenase gene as a second locus affected in poly(3-hydroxybutryic acid)-leaky mutants of Alcaligenes eutrophus", FEMS Microbiol. Lett. 97:227-234	
	СН	Oberg, B., and L. Vrang, 1990, "Screening for new agents", Eur. J. Clin. Microbiol. Infect. Dis. 9(7):466-471	
	CI	Yarchoan, R. and S.Broder, 1992 "Correlations between the <i>in vitro</i> and in vivo activity of anti-HIV agents: implications for future drug development", J. Enzym. Inhib. 6:99-111	
	CJ	Gait, M. and J. Karn, 1995, "Progress in anti-HIV structure-based drug design", TIBTECH 13(10):430-438	

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	CK	Flexner, C. and C. Hendrix, 1997, "Pharmacology of antiretroviral agents", in AIDS: Biology, Diagnosis, Treatment and Prevention, fourth edition, DeVita, Jr., V. et al., eds., Lippincott-Raven Publishers, pp. 479-493	
	CL	Pomerantz, R.J., et al., 1990, "Lipopolysaccharide is a potent monocyte/macrophage-specific stimulator of human immunodeficiency virus type 1 expression", J. Exp. Med. 172:253-261	
	СМ	Moriuchi, H., et al., 2000 "In vitro reactivation of human immunodeficiency virus 1 from latently infected, resting CD4 T cells after bacterial stimulation", J. Infect. Dis. 181(6):2041-4 (abstract provided)	
	CN	Sunshine, M., et al., 1997, "Mutation of the htrB gene in a virulent Salmonela typhimurium strain by intergeneric transduction: strain construction and phenotypic characterization", J. Bacteriol. 179(17):5521-5533	

EXAMINER

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